Endo Expands Voluntary Recall of Clonazepam Orally Disintegrating Tablets

Date: 11/19/2024

At Prime Therapeutics, we want to help you receive the best possible care. Visit our drug recall site for details: https://www.primetherapeutics.com/drugrecalls.

About this recall:
Endo is ***expanding*** its previously announced July 2024 voluntary recall of Clonazepam Orally Disintegrating Tablets (schedule IV controlled substance) due to potential product carton strength mislabeling.

The manufacturer's ongoing investigation has identified the possibility that the clonazepam product lots listed at the link on the following page could contain cartons printed with the incorrect strength and National Drug Code (NDC) code due to an error by a third-party packager. **The blister strips and tablets inside the product pack reflect the correct strength for each lot.**

The expanded recall includes the following 2 new NDCs: 49884-0310-02 (2 mg) and 49884-0309-02 (1 mg). The expansion also includes additional ***lots*** for the 2 NDCs included on the initial July 2024 recall: 49884-0306-02 (0.125 mg) and 49884-0307-02 (0.25 mg). The product is packaged in cartons containing 60 tablets packed into 10 blister strips each containing 6 tablets. **For lot recalls, the lot/batch information for the recalled products can be viewed by clicking on the link to the FDA Recall Notification found on the following page.**

Clonazepam Orally Disintegrating Tablets are indicated alone or for use as an add-on therapy for various seizure disorders (Lennox-Gastaut syndrome, akinetic, and myoclonic). Additionally, the product is approved for panic disorder.

What this means to you:
Children and adults who consume a higher dose of clonazepam than planned would be at risk for the adverse events of sedation, confusion, dizziness, decreased reflexes and muscle tone, as well as problems with coordination. The potential exists for significant, possibly life-threatening, breathing problems especially in patients with lung disease, patients receiving near maximal dosing, and patients taking other medications that could also cause problems breathing.

Consumers who have unused, recalled tablet cartons of Clonazepam Orally Disintegrating tablets with the lot numbers listed at the link below **should discontinue use of the product**. If a patient took an incorrect dose rather than the intended dose, they are advised to consult a health care professional. Consumers with questions regarding this recall can contact Inmar by telephone at 855-589-1869 (Monday through Friday, 9 a.m. to 5 p.m. ET) or by email at rxrecalls@inmar.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Mail: use postage-paid, pre-addressed Form FDA 3500 available at www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

This recall is being conducted with the knowledge of the United States (US) FDA.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-expands-voluntary-recall-clonazepam-orally-disintegrating-tablets-usp-c-iv-due-potential

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.